Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 20, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–14108 Filed 5–28–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0204]

QLT Phototherapeutics, Inc.; Premarket Approval of OPTIGUIDE™ Fiber Optic Diffuser (Models DCYL 10, DCYL 15, and DCYL 25), Coherent Lambda Plus™ PDL1 and PDL2 Photodynamic Lasers, and 600 Series Dye Modules (Models 630 and 630 XP) and Series 700 and 800 KTP/532® and KTP/YAG™ Surgical Lasers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the applications by QLT Phototherapeutics, Inc., submitted by Hogan & Hartson, Washington, DC on behalf of QLT Phototherapeutics, Inc., Vancouver, Canada, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the following devices which constitute the device portion of a combination drug/device product: OPTIGUIDE™ Fiber Optic Diffuser DCYL Series (Models DCYL 10, DCYL 15, and DCYL 25); Coherent Lambda Plus™ PDL1 and PDL2 Photodynamic Lasers; and 600 Series Dye Modules (Models 630 and 630 XP) and Series 700 and 800 KTP/532® and KTP/YAG™ Surgical Lasers. These devices are to be used with the drug PHOTOFRIN® under conditions specified in the drug labeling. After reviewing the recommendation of the Oncologic Drugs Advisory Committee operating under the authority of the Inter Agency Agreement regarding combination drug/device products, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 27, 1995, of the approval of the applications.

DATES: Petitions for administrative review by June 30, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard P. Felten, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1307.

SUPPLEMENTARY INFORMATION: On April 13, 1994, Hogan & Hartson, Washington, DC 20004–1109, submitted to CDRH, on behalf of QLT Phototherapeutics, Inc., Vancouver, Canada, applications for premarket approval of a combination drug/device product which included the following devices for use with the drug PHOTOFRIN®: (1) OPTIGUIDE™ Fiber Optic Diffuser DCYL Series; (2) Coherent Lambda Plus™ PDL1 and PDL2 Photodynamic Lasers; and (3) 600 Series Dye Modules (Models 630 and 630 XP) and Series 700 and 800 KTP/532® and KTP/YAG™ Surgical Lasers.

The Fiber Optic Diffuser is indicated as a delivery system for use in Photodynamic Therapy with PHOTOFRIN® for palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy. The laser systems are indicated for use in Photodynamic Therapy as sources for the photoactivation of PHOTOFRIN® for palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy.

On September 21, 1995, the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, operating under the authority of the Inter Agency Agreement for combination drug/device products, reviewed and recommended approval of the applications. On December 27, 1995, CDRH approved the applications by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

Summaries of the safety and effectiveness data on which CDRH based its approval are on file in the Dockets Management Branch (address above) and are available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve these applications. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 30, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the devices and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 18, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–13958 Filed 5–28–97; 8:45 am]

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